UNITED STATES DISTRICT COURT
FOR THE
NORTHERN DISTRICT OF NEW YORK

James J. Judge, as Executor of the Estate of Kevin F. Judge, deceased, Plaintiff, vs. LivaNova Deutschland GmbH (f/k/a Sorin Group Deutschland GmbH) and LivaNova Holding USA, Inc. (f/k/a Sorin Group USA, Inc.), Defendants,	Civil Action No. **5:18-cv-556 (GTS/ATB)** **COMPLAINT AND PLAINTIFF'S DEMAND FOR TRIAL BY JURY**

Plaintiff, James J. Judge, as Executor of the Estate of Kevin F. Judge, deceased, by his attorneys, James T. Snyder Law, PLLC and Weitz & Luxenberg, P.C., hereby complains of Defendants and alleges that, at all relevant times herein mentioned:

PARTIES, JURISDICTION AND VENUE

1. Decedent Kevin F. Judge (hereinafter "Decedent") lived in Syracuse, New York and was a citizen of Onondaga County in the State of New York.

2. Plaintiff James J. Judge (hereinafter "Plaintiff") lives in Syracuse, New York and is a citizen of Onondaga County in the State of New York. Plaintiff was appointed Executor of Decedent's estate by the Surrogate's Court of the State of New York, Onondaga County on March 14, 2016.

3. Defendant LivaNova Deutschland GmbH (f/k/a Sorin Group Deutschland GmbH) is a foreign corporation organized under the laws of Germany with its principal place of business at Lindberghstrasses 25, D-80939, Munich, Germany.

4. Defendant, LivaNova Holding USA, Inc. (f/k/a/ Sorin Group USA, Inc.) is incorporated under the laws of Delaware, with its principal place of business at 14401 W 65th Way, Arvada, Colorado 80004.

5. The amount in controversy exceeds $75,000.00 exclusive of interest and costs.

6. By reason of the diversity of citizenship of the parties and the amount in controversy this court has jurisdiction pursuant to 28 U.S.C. § 1332.

7. Venue is proper in the Northern District of New York pursuant to 28 U.S.C. §1391 because Defendants are subject to personal jurisdiction in the Northern District of New York, and thus, are residents of the Northern District of New York.

8. On November 2, 2011, Decedent was hospitalized at the St. Joseph's Hospital Health Center in Syracuse, New York for bioprosthetic aortic stenosis.

9. Upon information and belief, the Defendants designed, manufactured and marketed the Sorin Stöckert 3T Heater-Cooler system (hereinafter "Sorin 3T Heater-Cooler system" or "Sorin 3T Heater-Cooler device") used in Decedent's surgery.

10. The Defendants regularly do or solicit business within the State of New York, engage in other persistent conduct in the State of New York, and derive substantive revenue from goods used or consumed or services rendered in the State of New York, and their activities are so substantial and of such a nature that they are "at home" in the State of New York.

11. The Defendants have committed tortious acts outside the State of New York, causing injury to the Decedent within the State of New York, and Defendants expect or should reasonably expect such acts to have consequences in the State of New York, and derive substantive revenue from interstate or international commerce.

12. Defendants have targeted hospitals, surgeons and patients in New York, soliciting business, and engaging in persistent courses of conduct, to sell their medical devices including the Sorin 3T Heater-Cooler System.

13. A Sorin 3T Heater-Cooler device designed, manufactured, and marketed by Defendants was purchased by the St. Joseph's Hospital Health Center where it was used during the Decedent's surgery.

FACTUAL ALLEGATIONS

14. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

15. The Sorin 3T Heater-Cooler System provides temperature-controlled water to heat exchanger devices (cardio-pulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient's blood during cardio-pulmonary bypass procedures lasting six hours or less. The Sorin 3T Heater-Cooler System regulates blood temperature by circulating water through tubes into a heat exchanger where blood is pumped into separate chambers during surgery. The water tanks and other areas where water passes through aerosolize water contaminated with nontuberculous mycobacteria (NTM) which exits the device into the ambient air of the operating room by the system's exhaust fan. When used in an operating room, the contaminated vapor from the Sorin 3T Heater-Cooler System can enter the sterile surgical field and the patient's open body.

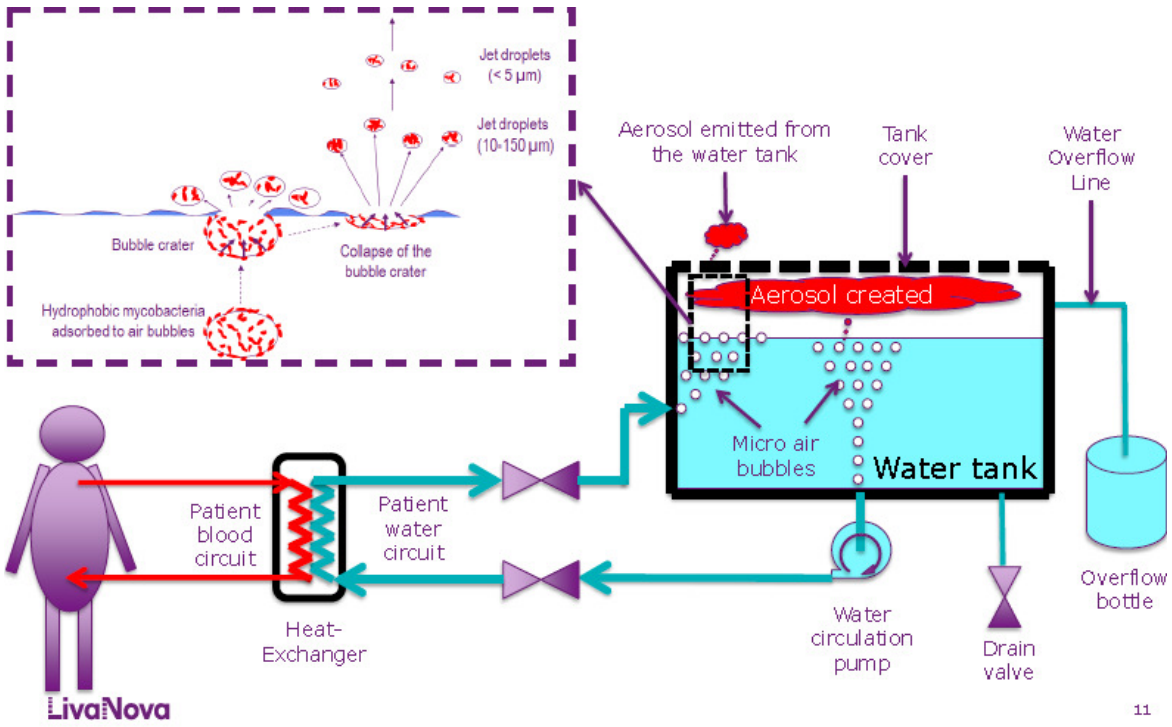

Figure 1 (from Defendants' publicly available presentation to the FDA Circulatory Devices Panel on June 2, 2016)

16. The Sorin 3T Heater-Cooler System is a Class II Medical Device that is subject to the Food and Drug Administration's ("FDA") Section 510K premarket notification process ("510K" or "510K process"), because that device is substantially equivalent to a legally marketed device that is not subject to premarket approval (PMA). 21 CFR 807.92(a)(3).

17. Prior to commercial distribution of the Sorin 3T Heater-Cooler System in the United States, the Defendants submitted a 510K notification of intent to market the Sorin 3T Heater-Cooler System with the Secretary of Health and Human Services for FDA approval.

18. The FDA determined that the Sorin 3T Heater-Cooler System was substantially equivalent to legally marketed predicate devices that do not require the more rigorous FDA Pre-Market Approval application process, which determination was relayed to the Defendants via letter on June 6, 2006, 510K number K052601.

19. The FDA approval allowed the Defendants to market the Sorin 3T Heater-Cooler System subject to the conditions and regulations in the approval letter.

20. Any commercial distribution of the Sorin 3T Heater-Cooler System that does not comply with the conditions set forth in the letter are violations of the Federal Food, Drug, and Cosmetic Act ("the Act").

21. Defendants were required to comply with all of the Act's requirements, including, but not limited to, Registration and Listing (21CFR part 807); Labeling (21CFR part 801); Good Manufacturing Practice Requirements as set forth in the Quality Systems Regulation (21CFR part 820); and, if applicable, the Electronic Product Radiation Control Provisions (Sections 531-542 of the Act); 21CFR 1000-1050.

22. On October 14, 2016, the St. Joseph's Hospital Health Center posted a news release on their web page regarding the Center for Disease Control's ("CDC") Quality Advisory, warning healthcare providers and patients who underwent open-chest or open-heart surgery in which a Sorin Stöckert 3T Heater-Cooler device was used, that they were potentially exposed to nontuberculous mycobacteria (NTM).

23. On October 31, 2016, St. Joseph's Hospital Health Center mailed Plaintiff a letter notifying him of the CDC's investigation of infections detected among several patients in other hospitals likely caused by bacterial contamination of heater-cooler devices used in open heart surgery. This letter confirmed to Plaintiff that "Kevin's infection was due to *Mycobacterium chimaera*" and that "the infection was probably acquired from a contaminated Stockert 3T heater-cooler device used in the operating room during his surgery in 2011".

24. NTM are most commonly found in water, soil, and dust, but if it enters the operative field, it poses a significant health risk to surgical patients.

25. Tissue that has been infected with nontuberculous mycobacterium usually presents as red, warm, tender to the touch, swollen, and/or painful and infected areas can appear as boils.

26. Additional signs and symptoms of the infection include fever, chills, muscles aches, and a general feeling of illness.

27. Diagnosis of NTM can be made from a laboratory analysis of a sample or biopsy of the infected area. In severe cases, the bacterium can be found in the blood and isolated from a blood sample. Targeted cultures, screenings, and proper testing are usually not performed unless the physician has been made aware of this type of mycobacterium exposure.

28. NTM infections are difficult to treat, and death of the infected patient is a severe risk. Treatments include draining collections of pus or removing the infected tissue, coupled with rigorous administration of a series of appropriate antibiotics for prolonged periods of time.

29. Published articles dating back to the 1980s confirm that NTM are commonly found in water and have a high propensity to become airborne (aerosolize) through natural processes.

30. The potential for contaminated water from heater-cooler devices to infect patients intraoperatively was known to the medical and scientific community as early as November 2002.

31. Invasive cardiovascular infections identified as NTM have been reported since 2011.

32. A public health investigation in Switzerland following six patient infections since 2011 included microbiological examinations of environmental samples that identified contamination by *Mycobacterium chimaera* (a species of NTM) in heater-cooler units, including water samples from inside the units. Samples of the ambient air were positive for *Mycobacterium chimaera* when the units were running, but negative when they were turned off.

33. In April, 2011, the FDA visited Defendant, LivaNova Deutschland GmbH (f/k/a/ Sorin Group Deutschland GmbH), in Munich, Germany for a plant inspection and to discuss safety concerns with several products, including the Sorin 3T Heater-Cooler System. The FDA advised the company that its Sorin 3T Heater-Cooler System harbored dangerous bacteria and that it had failed to make a proper risk assessment for cleaning the devices to avoid bacterial infections in patients exposed in the operating room.

34. Defendants admitted to the FDA that this particular patient risk was "not considered" because it was "not of concern."

35. During this inspection, the FDA advised the Defendants that the bacterial growth charts it used to justify the original instruction for device disinfection every 14 days allowed bacterial overgrowth well in excess of safe standards in just one and a half days. The company admitted to the FDA that its cleaning instructions did not meet these standards and that it had no information to support the cleaning methods it disseminated to U.S. purchasers.

36. In January, 2014, Sorin was notified of cases of NTM infection diagnosed in patients following open-heart surgery where a Sorin 3T Heater-Cooler Device was used.

37. In May, 2014, Defendants created a task force to investigate the risk of NTM infections from Sorin 3T Heater-Cooler Devices.

38. In July 2014, Defendants found NTM present in the water circuits of Sorin 3T Heater-Cooler Devices returned from the field. Thereafter, an "Important Information" letter was sent by Defendants to all Sorin 3T Heater-Cooler Device users, informing them of the risk of NTM infections and reminding them of the importance of water disinfection procedures in accordance with the manufacturer's Instructions for Use.

39. On July 15, 2015, the FDA issued a Class II Recall of the Sorin 3T Heater-Cooler System due to the "potential colonization of organisms, including mycobacteria, in Sorin Heater-Cooler Devices, if proper disinfection and maintenance is not performed per instructions for use."

40. The recall instructed all customers to follow revised Instructions for Use, which were outlined in a June 15, 2015 Field Safety Notice Letter for EU English-speaking countries, followed up by a similar letter to users in the United States on August 6, 2015, both issued by the Defendants' Director of Quality Assurance.

41. Defendants indicated that they were providing the Field Safety Notice Letters for the following reasons:

a. [To] remind [affected users] of the importance of following the company's disinfection and maintenance procedures;

b. [To] inform [affected users] that there is a possibility that bacteria can become aerosolized when the heater-cooler device is operated and serve as a source for contamination; and

c. [To] provide [affected users] with updated instructions for use regarding disinfection and maintenance procedures.

42. Upon information and belief, the Defendants knew or should have known that design and/or manufacturing defects in their Sorin 3T Heater-Cooler System made it susceptible to NTM colonization, notwithstanding utilizing the cleaning and disinfection procedures outlined in the Defendant's instructions.

43. On December 29, 2015, the FDA issued a Warning Letter to the Defendants, which stated that its inspection of Sorin's facilities in Germany and Colorado revealed that the Sorin 3T Heater-Cooler System devices had been "adulterated," meaning the "methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation [were] not in

conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.".

44. The FDA noted several other violations by the Defendants in said Warning Letter, which include, but are not limited to, the following:

a. Failure to establish and maintain procedures for the identification, documentation, validation or, where appropriate, verification, review, and approval of design changes before their implementation, as required by 21 CFR 820.30(i);

b. Failure to validate a process, with a high degree of assurance and approved according to established procedures, a process where results cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a);

c. The devices were misbranded in that Sorin failed or refused to furnish material or information respecting the device that is required by or under § 519 of the Act 21 USC § 360i and 21 CFR Part 803 – Medical Device Reporting;

d. Failure to adequately develop, implement, and maintain written MDR procedures, as required by 21 CFR 803.17;

e. Defendants' Sorin 3T System was misbranded due to its failure to notify the agency of its intent to introduce the device into commercial distribution as required by § 510(k) of the Act, 21 USC §360(k); and

f. Failure to notify the agency of significant labeling changes that affected the safety and effectiveness of the device (e.g., distributing the device with modified instructions for use with respect to the operating, maintaining, cleaning, and disinfecting of the device, among other modifications).

45. In April, 2016, a Euro Surveillance study following environmental investigations conducted between July, 2014 and June, 2015 determined that certain Sorin 3T Heater-Cooler Systems manufactured at Defendants' Munich, Germany production facility were contaminated with NTM on the production line or elsewhere at Defendants' manufacturing facility.

46. On June 1, 2016, an FDA Safety Communication following the Euro Surveillance findings noted that "this paper suggests a direct link between the M Chimaera to which European

patients were exposed and became infected during open-chest cardiac surgery, and one specific heater-cooler model – the 3T." The FDA cautioned U.S. purchasers of the Sorin 3T Heater-Cooler System that if they purchased their units before September, 2014, they may have been shipped from Defendants' factory contaminated with *Mycobacterium chimaera*.

47. Contrary to the Defendants' representations to the FDA, medical community and to patients, Defendants' Sorin 3T Heater-Cooler System has high injury and complication rates, fails to perform as intended, requires patients to undergo additional operations, and has caused severe and sometimes irreversible injuries, conditions, and damages to a significant number of patients, including the Decedent, all of which are violations of federal and New York rules and regulations.

48. In June, 2016, a study published in the Journal of Emerging Infectious Diseases confirmed the airborne transmission of NTM via Sorin 3T Heater-Cooler Systems due to the ability of the System's exhaust fan to disrupt the ultraclean air ventilation systems of operating rooms. According to the study, aerosolization from the Sorin 3T Heater-Cooler System carried *Mycobacterium chimaera* particles a distance of up to 5 meters from the device.

49. On June 2-3, 2016, the FDA hosted a Circulatory System Devices Panel for the Medical Devices Advisory Committee to address the public health risk posed by heater-cooler devices, and in particular, the Sorin 3T Heater-Cooler System.

50. During this Panel, the FDA noted that nearly 90% of the Medical Device Reports ("MDR") it received between January 2010 and February 2016 citing device contamination and patient infection were attributed to the Sorin 3T Heater-Cooler System.

51. During this Panel, Defendants' representative admitted that the Defendants were in the process of retrofitting Sorin 3T Heater-Cooler Systems with new design features, including,

but not limited to, changing tubing materials from PVC to polyethylene to limit biofilm contamination and the introduction of plugs in the water circuit to prevent sitting water.

52. On October 13, 2016, the CDC released the results of genome sequencing studies confirming that patient infections in Pennsylvania and Florida were directly linked to Defendants' Munich, Germany manufacturing site.

53. On October 13, 2016, the FDA issued an updated Safety Communication instructing hospitals throughout the country to discontinue using Sorin 3T Heater-Cooler Systems manufactured before September 14, 2016 due to evidence of "point source contamination at the production site."

54. In violation of federal and New York requirements, the Defendants consistently under-reported and withheld information about the propensity of the Sorin 3T Heater-Cooler System to experience complications and its failure to perform as expected, has misrepresented the efficacy and safety of Defendants' system through various means and media and misled the FDA, the medical community, patients, and the public at large.

55. Defendants knew that its disclosures to the FDA, the public, Decedent and Plaintiff were, and are, incomplete and misleading and that the Sorin 3T Heater-Cooler System was and is causing numerous patients severe injuries and complications, which violates Federal and New York requirements. Defendants willfully suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, the medical community, health care providers, and patients. As a result, the Defendants actively and intentionally misled the FDA and the public, including the medical community, healthcare providers, and patients, into believing that the Sorin 3T Heater-Cooler System was safe and

effective, leading to the use of Defendants' system during surgical procedures, such as the one undergone by Plaintiff, as more fully described herein.

56. In violation of federal and New York rules and regulations, the Defendants failed to perform and/or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Sorin 3T Heater-Cooler System.

57. As compared to similar systems, feasible and suitable alternative designs, procedures, and instructions for use were in existence and available.

58. The Defendants' Sorin 3T Heater-Cooler System was utilized in a manner foreseeable to the Defendants.

59. In order to increase its sales to hospitals and physicians utilizing the device, the Defendants provided incomplete, insufficient, and misleading instructions, training, and information to hospitals and physicians, in direct violation of federal and State regulations and in violation of regulations required pursuant to the 510K Approval of the Sorin 3T Heater-Cooler System.

60. The Sorin 3T Heater-Cooler System used during Decedent's surgical procedure was in the same or substantially similar condition as it was when it left the possession of the Defendants.

61. The injuries, conditions, and complications Decedent suffered due to the Sorin 3T Heater-Cooler System include, but are not limited to, infection, excruciating pain, weakness, excessive additional and debilitating medical treatment, suffering and death.

62. Despite Defendants' knowledge of the catastrophic injuries, conditions, and complications caused by the Sorin 3T Heater-Cooler System, in violation of federal and New York requirements, it continued to manufacture, market, provide inadequate instructions for use, and

sell the Sorin 3T Heater-Cooler System, and also failed to adequately warn, label, instruct, and disseminate information with regard to Defendants' Sorin 3T Heater-Cooler System both prior to and after the manufacture, marketing, and sale of the System.

FACTS SPECIFIC TO THIS CASE

63. On November 2, 2011, Decedent, Kevin F. Judge underwent replacement of his aortic valve, ascending aorta and a redo Bentall procedure with bioprosthetic valve at St. Joseph's Health Center in Syracuse, New York for bioprosthetic aortic stenosis and ascending aortic aneurysm. Defendants' Sorin 3T Heater-Cooler System was used during this November 2, 2011 operation, during which Kevin F. Judge's surgeon used the device to provide cooling and re-warming of Kevin F. Judge's blood.

64. On March 5, 2014, Kevin F. Judge was hospitalized at St. Joseph's Hospital Health Center in Syracuse, New York for a mediastinal pseudoaneurysm. On March 7, 2014, Kevin F. Judge underwent multiple surgical procedures including, but not limited to, a redo sternotomy, redo Bentall procedure, and reimplantation of right and left coronary ostium. During this surgery, a very large aortic root abscess with pus was found. Cultures were taken from said abscess and sent for analysis. He was also seen by the infectious disease department at St. Joseph's Hospital Health Center whereas he was noted to have daily fevers ranging to approximately 105 degrees Fahrenheit.

65. Several weeks later on March 31, 2014, analysis results of the cultures taken during Decedents's March 7, 2014 surgery diagnosed an infection, *Mycobacterium avium-intracellulare* complex ("MAI" also known as "MAC"). Decedent was subsequently readmitted to St. Joseph's Hospital Health Center on May 2, 2014, by the referral of Dr. Jacoby for placement of a peripherally inserted central catheter ("PICC") line and delivery of long-term

intravenous antibiotics (amikacin). The indication for this treatment was "mycobacterium avium aortic root abscess".

66. On July 16, 2014, Decedent was readmitted to St. Joseph's Hospital Health Center for hypercalcemia which was determined to be due to his MAI infection and treated with prednisone.

67. On July 21, 2015, Decedent was again admitted to St. Joseph's Hospital Health Center for periaortic fluid collection aspiration from an enlarging aortic root abscess observed on a recent CT scan. Laboratory cultures of fluid drained from the abscess returned a positive result for MAI.

68. On August 19, 2015, Decedent was again hospitalized at St. Joseph's Hospital Health Center for his aortic root abscess with MAI and additional complications. Due to his overall deterioration, Decedent was discharged from St. Joseph's Hospital Health Center on August 29, 2015 and transferred to the Cleveland Clinic in Cleveland, Ohio for further care.

69. On September 14, 2015, Decedent underwent another procedure at the Cleveland Clinic for chest exploration, abscess drainage and placement of irrigation catheters. His treatment at the Cleveland Clinic continued until he was discharged on October 10, 2015 and sent to the Centers at St. Camillus in Syracuse, New York for rehabilitation.

70. On October 19, 2015, Decedent was transferred from the Centers at St. Camillus to the emergency department at St. Joseph's Hospital Health Center where he was found to be in septic shock. Decedent was then transferred to the intensive care unit where he was aggressively treated with intravenous antibiotics and other medications for an MAI infection.

71. On October 25, 2015, Kevin F. Judge passed away at St. Joseph's Hospital Health Center. There were several final diagnoses including, but not limited to infection and

inflammatory reaction due to cardiac valve prosthesis, other mycobacterial infections, sepsis unspecified organism (Primary) and severe sepsis with septic shock. Decedent, Kevin F. Judge's death certificate listed the cause of death as "infected prosthetic aortic valve".

72. Plaintiff, James J. Judge received a letter dated October 31, 2016 from the infectious disease department at St. Joseph's Hospital Health Center notifying him of the CDC's investigation of infections caused by the Sorin Stöckert 3T heater-cooler system due to contamination with *Mycobacterium chimaera*. The October 31, 2016 letter is the first time Decedent was diagnosed with having had a *Mycobacterium chimaera* infection.

73. At no point prior to October 2016 was *Mycobacterium chimaera* identified as the organism causing Decedent's infection. At no point prior to October 2016 was Decedent or Plaintiff ever notified of the relationship between usage of the Sorin Stöckert 3T heater-cooler device and infection with *Mycobacterium chimaera*.

74. Decedent's serious injuries as a result of his *Mycobacterium chimaera* infection from usage of the Sorin Stöckert 3T heater-cooler system have caused and led to his death. Decedent is survived by Plaintiff, James J. Judge, as Executor of his Estate.

EQUITABLE TOLLING OF APPLICABLE STATUTES OF LIMITATIONS

75. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

76. Plaintiff pleads all Counts in this Complaint in the broadest sense, pursuant to all laws that may apply according to choice of law principles, including the law of the Decedent and Plaintiff's resident State.

77. Filing of this action is timely and within the applicable statute of limitations, as the filing date, pursuant to a stipulation amongst the parties, relates back to June 30, 2017.[1]

78. Plaintiff also asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including but not limited to equitable tolling, class action tolling, delayed discovery, discovery rule and fraudulent concealment.

79. Decedent's injury and its relationship to the Sorin 3T Heater-Cooler System was not discovered, and through reasonable care and due diligence could not have been discovered, until approximately October 2016. Plaintiff's suit was filed well within the applicable statutory limitations period.

80. The statute of limitations in this case was equitably tolled and Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through affirmative misrepresentations and omissions, from Decedent and Plaintiff, Decedent's treating physicians and/or the public of the true risks associated with the Sorin 3T Heater-Cooler System. As a result of the Defendants' fraudulent concealment, Decedent and Plaintiff, and/or Decedent's physicians were unaware, and could not have known or have learned through reasonable diligence, that Decedent had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

81. Furthermore, the Defendants are estopped from relying on any statute of limitations because of their concealment of the truth, quality and nature of the Sorin 3T Heater-

[1] Attached hereto as Exhibit A, is the stipulation signed by M. Joseph Winebrenner on behalf of Defendants Sorin Group Deutschland GMBH and Sorin Group USA, Inc. and David L. Rosenband on behalf of Plaintiff James J. Judge. Per the stipulation, "The date of the re-filing of this complaint in federal court shall relate back to June 30, 2017, the original filing date of this matter in the Supreme Court County of Onondaga."

Cooler System. The Defendants were under a duty to disclose the true character, quality and nature of the Sorin 3T Heater-Cooler System because this was nonpublic information over which the Defendants had and continue to have exclusive control, and because the Defendants knew that this information was not available to Decedent or Plaintiff, Decedent's medical providers and/or to his health facilities.

82. The Defendants failed to make to the consuming public and medical professionals, timely and full disclosure in a manner reasonably calculated to reach all persons using (such as the Decedent) and all physicians utilizing the Sorin 3T Heater-Cooler System, the full extent and nature of the attendant risks and known or reasonably known dangers of using the Sorin 3T Heater-Cooler System. The Defendants failed to maintain a contemporaneous database of medical providers that used the Sorin 3T Heater-Cooler System and/or persons to whom the Sorin 3T Heater-Cooler System caused injury or death. The Defendants failed to report contemporaneous instances of injury or death caused by the Sorin 3T Heater-Cooler System.

83. The defects of the Sorin 3T Heater-Cooler System are latent and self-concealing. Even in the exercise of reasonable care, Decedent and Plaintiff could not have discovered that such inherent defects existed. By suppressing the dissemination of information regarding the hazards, dangers and attendant risks of using the Sorin 3T Heater-Cooler System, the Defendants intentionally foreclosed Decedent and Plaintiff from learning of the relationship between the Sorin 3T Heater-Cooler System's defects and Decedent's latent injuries.

84. Defendants had the ability to and did spend enormous amounts of money in furtherance of their purpose of marketing and promoting a profitable medical device, notwithstanding the known or reasonably known risks. Plaintiff, Decedent and/or his medical professionals could not have afforded and could not have possibly conducted studies to

determine the nature, extent and identity of related health risks and, instead, were forced to rely on Defendants' representations.

85. Defendants were and continue to have information and data within their exclusive possession and control that show the risk and dangers that the Sorin 3T Heater-Cooler System causes, which was/is not otherwise in the possession or available to Plaintiff, Decedent and/or his healthcare providers.

86. At the time of Decedent's injuries, Plaintiff, Decedent and/or Decedent's healthcare providers were not aware of any facts which would have made a reasonably prudent person suspicious of Defendants' wrongdoing because Plaintiff, Decedent and Decedent's healthcare providers reasonably relied on Defendants' representations that the Sorin 3T Heater-Cooler System was safe for use. Plaintiff and Decedent had no knowledge that the Defendants were engaged in the wrongdoing alleged herein.

87. At no time prior to Plaintiff's eventual discovery of wrongdoing did any of Decedent's doctors ever inform, advise, suggest or otherwise imply that the Sorin 3T Heater-Cooler System use was a potential contributing cause of Decedent's infection and adverse event(s).

88. Plaintiff and Decedent reasonably relied on the skill and judgment of Decedent's doctors and had no reason to further investigate, inquire into or suspect that the Sorin 3T Heater-Cooler System caused Decedent's conditions.

89. Plaintiff and Decedent exercised reasonable diligence in an attempt to discover the cause of Decedent's infection. Plaintiff and Decedent relied on his physicians to advise him of any known complications. Plaintiff and Decedent had no reason to believe his injuries were

the result of any wrongdoing, whether intentional and/or negligent, until the discovery dates suggested below and are therefore relying on the benefit of the discovery rule.

90. Plaintiff and Decedent had neither knowledge nor reason to suspect that the Defendants were engaged in the wrongdoing alleged herein. Because of the fraudulent acts of concealment and wrongdoing by the Defendants, Plaintiff and Decedent could not have reasonably discovered the wrongdoing at the time of his injury.

91. At the time of Decedent's injuries, neither Decedent nor Plaintiff had access to or actually receive any studies or information recognizing the increased risk of *Mycobacterium chimaera* infection caused by use of the Sorin 3T Heater-Cooler System or have any discussions with his doctors that there was an association between his infection and/or injuries and use of the Sorin 3T Heater-Cooler System.

92. By letter dated October 2016, the St. Joseph's Hospital Health Center Infectious Disease department notified Plaintiff for the very first time that Decedent was diagnosed with having had a *Mycobacterium chimaera* infection which "was probably acquired from a contaminated Stockert 3T heater-cooler device used in the operating room during his surgery in 2011".

93. Prior to his death, Decedent, as well as Plaintiff, had never been informed that he was infected with *Mycobacterium chimaera*. Thus the cause of the injury was discovered less than five years after discovery of the injury and with reasonable diligence such injury could not have been discovered, and this action was commenced within one year of discovery of the cause of injury.

94. Technical, scientific or medical knowledge and information sufficient to ascertain the cause of the injury had not been discovered, identified or determined prior to the expiration

of the period within which the action or claim would have been authorized and Plaintiff has otherwise satisfied the requirements of NY CPLR § 214-c two and three.

95. Prior to October 2016, Plaintiff and Decedent did not have access to, or actually receive any studies or information recognizing the increased risk of *Mycobacterium chimaera* infection with use of the Sorin 3T Heater-Cooler System. As such, prior to October 2016, Plaintiff and Decedent had no knowledge of the injury or the cause of his injury and were not aware of the increased risk of infection with *Mycobacterium chimaera* associated with the use of the Sorin 3T Heater-Cooler System.

96. The self-concealing nature of the Defendants' actions and their intentional concealment of wrongdoing formed the basis of Plaintiffs' assertion and demand that any and all applicable statute of limitations affecting the claims of Plaintiff be tolled if this is made an issue by Defendants.

AS AND FOR A 1st CAUSE OF ACTION – NEGLIGENCE

97. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

98. The Defendants owed a duty of reasonable care to the general public, including Plaintiff and Decedent, when it designed, labeled, manufactured, assembled, inspected, tested, marketed, placed into the stream of commerce, instructed, and sold the Sorin 3T Heater-Cooler System, to assure that the product was in compliance with FDA regulations and not defective or unsafe for its intended purposes and uses.

99. The Defendants breached this duty by negligently designing, labeling, manufacturing, assembling, inspecting, testing, marketing, distributing, instructing, and selling the Sorin 3T Heater-Cooler System in a defective and unsafe condition.

100. The Defendants owed Decedent and Plaintiff a duty of reasonable care to discover defects and/or errors in the machine and to inform and/or warn the FDA and the medical community of any danger once it was discovered. The Defendants violated these duties when they failed to do so, which further placed Decedent at risk for harm and injury.

101. The Sorin 3T Heater-Cooler System differed in design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution and advertising from the system that received approval through the 510K process, and thus the design, manufacture, packaging, storing, warning, labeling, instructions for use, distribution and advertising of the Sorin 3T Heater-Cooler System used at St. Joseph's Hospital Health Center during Decedent's heart procedure was done in violation of federal and state statutes, rules and regulations.

102. The Defendants had the duty to comply with and not deviate from requirements which, amongst other things, require that the device be manufactured, labeled, and designed and marketed according to the standards submitted for FDA approval. The Defendants violated these duties when they failed to comply therewith and deviated from the regulatory requirements.

103. The Defendants negligently misrepresented to the FDA, the medical community, Decedent and Plaintiff, and the public, the dangers and extent of adverse reactions and labeling and instruction errors of the Sorin 3T Heater-Cooler System.

104. The Defendants failed to adhere to FDA regulations by failing to appropriately report all of the information and knowledge in their possession in regards to the dangers that the Defendants knew their product presented, including, but not limited to, the fact that colonization of Mycobacteria inside the Sorin 3T Heater-Cooler System could occur if adequate disinfection and maintenance procedures were not implemented or followed.

105. Defendants knew that the Sorin 3T Heater-Cooler System was defective and unreasonably unsafe for intended purposes, but the Defendants failed to properly report this to the FDA.

106. The Defendants were under a duty to disclose to the FDA, Decedent/Plaintiff, and the medical community, the defective nature and extent of adverse reactions and labeling errors of the system.

107. The Sorin Stöckert 3T heater-cooler device was negligently designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed by Defendants due to inadequate post-marketing surveillance and/or warnings because, after Defendants knew or should have known of the risks of serious side effects, as well as other severe and permanent health consequences from the Sorin Stöckert 3T heater-cooler device. Defendants negligently failed to communicate these findings to the FDA or to provide adequate warnings to users or consumers of the product, and continued to improperly advertise, market and/or promote their product.

108. Decedent's infection was caused by Defendant's negligent conduct as follows:

a. Failing to provide proper cleaning and disinfection instructions for the Sorin 3T System;

b. Failing to conduct adequate validation studies to demonstrate the safety and efficacy of cleaning and disinfection procedures for the Sorin 3T System;

c. Failing to warn patients like the Decedent and/or purchasers of the Sorin 3T System that the system colonized bacteria and unnecessarily transmitted it into the ambient air of operating rooms;

d. Failing to timely notify known purchasers of the Sorin 3T System that patients could be exposed to *Mycobacterium chimaera*;

e. Failing to alert hospitals and patients to promptly test for NTM infection when patients present with fever, pain, heat or pus around a surgical incision, night

sweats, join and muscle pain, weight loss and fatigue after surgery using the Sorin 3T System; and

f. Failing to timely notify known purchasers of the Sorin 3T System to relocate the device from the operating room during surgery to prevent patient transmission of NTM.

109. Had the Defendants accurately and truthfully represented to the FDA, the medical community, Decedent, Plaintiff, and the public, the material facts relating to the risks of the Sorin 3T Heater-Cooler System, Plaintiff, Decedent and/or Decedent's healthcare provider would not have utilized the Sorin 3T Heater-Cooler System as they did during Decedent's heart procedure.

110. Due to the aforesaid negligence Decedent suffered severe personal injury, including but not limited to pain, suffering and loss of enjoyment of life, and was caused to expend monies for medical care.

111. Defendants acted intentionally, recklessly and wantonly without regard for Decedents's rights beyond all standards of decency, entitling Plaintiff to recover punitive damages.

112. The limitations set forth in Article 16 of the New York Civil Practice Law and Rules are inapplicable because the Defendants acted knowingly and intentionally in concert (CPLR 1602-11).

113. Pursuant to NY EPTL § 11-3.2, Plaintiff demands, by virtue of the aforesaid negligence, judgment in his favor for compensatory and punitive damages, together with interest, costs, and attorneys' fees in a sum greater than $75,000.00.

AS AND FOR A 2nd CAUSE OF ACTION – STRICT PRODUCTS LIABILITY

114. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

115. The Sorin 3T Heater-Cooler System was defective and unreasonably dangerous to consumers, including Decedent, in normal use.

116. The Sorin 3T Heater-Cooler System was expected to and did reach the usual health care consumers and surgeons coming into possession of said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants.

117. When it left the hands of the Defendants, the Sorin 3T Heater-Cooler System was defective and the risks of use of said product exceeded the benefits associated with it.

118. The Sorin 3T Heater-Cooler System was defective in that, when it left the hands of the Defendants, it was unreasonably dangerous, and more dangerous than an ordinary consumer or patient would have expected.

119. At the time of the Decedent's treatment with the Sorin 3T Heater-Cooler System, the device was being used for the purposes and in a manner normally intended to provide temperature-controlled water to heat exchanger devices (cardio-pulmonary bypass heat exchangers, cardioplegia heat exchangers, and thermal regulating blankets) to warm or cool a patient's blood during cardio-pulmonary bypass procedures lasting six (6) hours or less.

120. By reason of the foregoing, the Defendants are strictly liable in tort to the Plaintiff for the manufacturing, marketing, promoting, distribution, and selling of a defective product.

121. Defendants' defective design, manufacturing defect, and inadequate warnings of the Sorin 3T Heater-Cooler System caused Decedent's injuries.

122. As a result of the foregoing, Decedent was caused to suffer serious and dangerous side effects as well as other severe and personal injuries which are permanent and lasting in nature,

physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications.

123. Plaintiff demands judgment in a sum that exceeds the jurisdictional limits of all lower courts.

AS AND FOR A 3rd CAUSE OF ACTION – FAILURE TO WARN

124. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

125. Defendants marketed, advertised, and promoted the Sorin 3T Heater-Cooler System for the purpose of heating and cooling patient blood during major heart, lung and liver surgeries.

126. Defendants knew or should have known as early as 2002 that nontuberculous mycobacteria, or other harmful bacteria, could colonize within the Sorin 3T Heater-Cooler System and be spread to patients during surgery through the exhaust vent.

127. Decedent was proximately harmed by the aforesaid inadequate warnings as described above.

128. Plaintiff requests judgment for compensatory and punitive damages, together with interest, costs herein incurred, attorney's fees, and all such other and further relief as this Court deems just and proper.

AS AND FOR A 4th CAUSE OF ACTION – BREACH OF IMPLIED WARRANTY

129. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

130. Defendants impliedly warranted, through its marketing, advertising, distributors and sales representatives, that the Sorin 3T Heater-Cooler System was of merchantable quality, and fit for the ordinary purposes and uses for which it was sold.

131. In fact, said Sorin 3T Heater-Cooler System was not of merchantable quality nor fit for the ordinary purposes and uses for which it was sold and did not meet the expectations of consumers.

132. By reason of the aforesaid, Defendants breached their implied warranty of merchantability.

133. As a direct and proximate result of the Defendants' breach of the aforementioned implied warranty, Decedent has suffered injury and has further experienced significant mental and physical pain and suffering, underwent rigorous and debilitating medical treatment, death, suffered financial and/or economic loss, including, but not limited to, obligations for medical services and expenses, and other damages.

134. By reason of the aforesaid, Plaintiff demands judgment against Defendants in a sum that exceeds the jurisdictional limits of all lower courts.

AS AND FOR A 5th CAUSE OF ACTION – VIOLATION OF NEW YORK'S GENERAL BUSINESS LAW § 349

135. Plaintiff herein incorporates paragraphs 1-107 as if fully set forth herein.

136. The aforesaid acts, representations and/or omissions by the Defendants constitute unconscionable commercial practices in connection with the sale of merchandise and false advertising and were materially deceptive and misleading practices aimed at the consumer public at large.

137. Defendants violated New York General Business Law § 349.

138. By virtue of said violation, Decedent suffered detriment and injury and Plaintiff is entitled to damages, costs, disbursements and attorney fees in a sum that exceeds the jurisdictional limits of all lower courts.

AS AND FOR A 6th CAUSE OF ACTION – WRONGFUL DEATH

139. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

140. Due to the aforesaid actions of Defendants and as a direct and proximate result of the Defendants' wrongful conduct, Decedent, Kevin F. Judge, suffered fatal injuries and expired, leaving his distributes and siblings James J. Judge, Carol A. Judge and Mark E. Judge.

141. Plaintiff, James J. Judge, was issued Letters Testamentary naming him Executor of Decedent's estate by the Surrogate's Court of the State of New York, Onondaga County on March 14, 2016.

142. By reason of the above Plaintiff, James J. Judge, as representative of the Estate of Kevin F. Judge, is entitled to recover wrongful death damages in a sum greater than $75,000.00.

AS AND FOR A 7th CAUSE OF ACTION – SURVIVAL ACTION NY EPTL § 11-3.2

143. Plaintiff incorporates by reference each preceding and succeeding paragraph as though set forth fully at length herein.

144. By reason of the aforesaid, Plaintiff is entitled to recover damages for the Decedent's pain and suffering and loss of enjoyment of life pursuant to NY EPTL § 11-3.2.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages in a sum greater than $75,000.00, together with interest, costs, attorneys' fees and such other relief as may be available to them.

New York, NY
Dated: **May 9, 2018**

Yours, etc;

By /s/ James T. Snyder

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